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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,556	11/16/2001	Jordan U. Gutterman	CLFR:009US	5224
7590 02/21/2008				
Robert E. Hanson FULBRIGHT & JAWORSKI L.L.P. SUITE 2400 600 CONGRESS AVENUE AUSTIN, TX 78701		EXAMINER WEBB, WALTER E		
		ART UNIT 1612		PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/992,556	Applicant(s) GUTTERMAN ET AL.	
	Examiner Walter E. Webb	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 3-8, 11-20, 33-38, and 53-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 9, 10, 21-32 and 39-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | *5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :4/23/2007, 11/10/2003, 6/6/2002.

DETAILED ACTION

Status of Claims

Claims 1-55 are pending.

Claims 3-8, 11-20, 33-38, and 53-55 are withdrawn from consideration.

Claims 1, 2, 9, 10, 21-32, and 39-52 are currently under examination.

Election/Restrictions

Applicant's election without traverse of Group I (claims 1, 2, 9, 10, 21-32, and 39-52) in the reply filed on January 11, 2008 is acknowledged.

Claims 3-8, 11-20, 33-38, and 53-55 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on January 11, 2008.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 9, 10, 21-32, and 39-52 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibiting a specific type of inflammation in SKH-1 hairless mice, does not reasonably provide enablement for inhibiting inflammation in general. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include:

- 1) the nature of the invention;
- 2) the breadth of the claims;
- 3) the predictability or unpredictability of the art;
- 4) the amount of direction or guidance presented;
- 5) the presence or absence of working examples;
- 6) the quantity of experimentation necessary;
- 7) the state of the prior art; and,
- 8) the relative skill of those skilled in the art.

The relevant factors are addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

Factors 1 and 2: The claimed invention is drawn to a method of inhibiting inflammation by administering to a cell a monoterpene composition that inhibits NF-kB (claim 1).

Factors 3 and 7: In particular, one skilled in the art could not practice the presently claimed subject matter without undue experimentation because the artisan would not accept on its face that inhibiting inflammation in general, could be effectively achieved by the administration of the claimed active agent. Based on the state of the art, as discussed below, the artisan would have only accepted that the inhibition of specific inflammatory conditions in hairless mice could be achieved, rather than that such an agent could have been used to inhibit inflammation in general.

As set forth in *In re Marzocchi et al.*, 169 USPQ 367 (CCPA 1971):

"[A] [s]pecification disclosure which contains teaching of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with the enabling requirement of first paragraph of 35 U.S.C. 112 unless there is reason to doubt the objective truth of statements contained therein which must be relied on for enabling support; assuming that sufficient reasons for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis, such a rejection can be overcome by suitable proofs indicating that teaching contained in the specification is truly enabling."

Factor 4: Applicant disclosed how the claimed active agent regulates Nf-kB and how a human or animal might be administered the active agent. Still, applicant set forth

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no protocol as to how inhibition of any inflammation could be achieved. Applicant's disclosure is inadequate as to directing or guiding how the proposed agent(s) can be employed to accomplish such objectives in a predictable manner.

Factor 5: The specification at pages 253-254 provides evidence demonstrating that the composition reduces inflammatory signals in SKH-1 hairless mice. While the present claims encompass inhibiting inflammation in general, Applicant's data merely establishes a reduction in the inflammatory response of SKH-1 hairless mice. No data has been provided, or reasonable scientific basis exists, for treating such results as inhibition of inflammation in general.

There are many types of inflammation, which are associated with many different disease states. For illustration purposes only the examiner will focus on rheumatoid arthritis and asthma as two representative disease states. Effectively inhibiting inflammation in the treatment of rheumatoid arthritis and asthma for example, is unpredictable (see Vane et al., "Inflammation and the mechanism of action of anti-inflammatory drugs." FASEB J. 1987).

In this regard, the Vane et al. is cited. In particular, there is no known agent that is effective against stopping the progression of arthritis or asthma effectively. The Vane reference clearly shows that for different types inflammatory mediators, there is not one agent or combination thereof that is effective at inhibiting inflammation in general, since asthma or arthritis cannot be effectively inhibited (see Abstract, and Conclusion at pg. 95).

Given that there was not known a specific agent or combination of agents effective to inhibit chronic inflammation associated with rheumatoid arthritis and asthma, one of ordinary skill in the art would not accept on its face Applicant's statement that the claimed active agent could inhibit inflammation in general. The artisan would have required sufficient direction as to how to predict what particular types of inflammation would actually show sensitivity to the presently claimed composition such that the artisan would have been imbued with at least a reasonable expectation of success in inhibiting inflammation in general. Such success would not have been reasonably expected for inhibiting inflammation given the difficulties in treating rheumatoid arthritis. The inhibition of inflammation in general would have been an outcome not reasonably expected by one of ordinary skill in the art. To the artisan, the concept of a single agent, or even a combination of agents, that is effective to inhibiting inflammation in general would have been unique and, thus, met with a great deal of skepticism.

The Examiner acknowledges that the Office does not require the presence of working examples to be present in the disclosure of the invention (see MPEP §2164.02). However, in light of the state of the art, which recognizes the unpredictable nature of treating rheumatoid arthritis and asthma, there is no apparent disclosure to support the contention that any inflammation can be inhibited by simply administering, by any method, a monoterpene, since the present specification fails to enable one of ordinary skill in the art to practice the entirety of the presently claimed invention.

Factor 6: The burden of inhibiting inflammation generally with the claimed composition is much greater than that of treating a specific type of inflammation with the

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claimed composition. Since the present specification would not enable the skilled artisan to inhibit inflammation generally with the claimed composition, a clear burden of undue experimentation would be placed upon the skilled artisan in order to practice the full scope of the presently claimed invention.

Factor 8: In view of the discussion of each of the preceding seven factors, the level of skill in this art is high and is at least that of a medical doctor with several years of experience in the art.

Summary

As the discussion of the above 8 factors establish, practicing the claimed method in the manner disclosed by Applicant would not imbue the skilled artisan with a reasonable expectation that inhibiting inflammation generally with the claimed composition could be achieved. In order to actually achieve such an objective, it is clear from the discussion above that the artisan could not rely on Applicant's disclosure as required by 35 U.S.C. § 112, first paragraph. Given that the art fails to recognize, and Applicant as failed to demonstrate, via direct evidence or sound reasoning, that inflammation generally can be inhibited with the claimed composition, the artisan would be faced with the impermissible burden of undue experimentation in order to practice this embodiment of the claimed invention. Accordingly, claims 1, 2, 9, 10, 21-32, and 39-52 are deemed properly rejected.

Claims 1, 2, 9, 10, 23 and 39-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, Applicant discloses a method of inhibiting inflammation by administering a monoterpene.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See. E.g., *In re Wilder*, 22 USPQ 369, 372-3 (Fed. Cir. 1984). (Holding that a claim was not adequately described because the specification did 'little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.')

Mere indistinct terms (such as "monoterpene" used herein), however, may not suffice to meet the written description requirement. This is particularly true when a compound is claimed in purely functional terms. See *Univ. of Rochester v. G.D. Searle*, 69 USPQ2d 1886 (CAFC 2004) at 1892, stating:

The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice. . . . The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

Conversely, a description of a chemical genus will usually comprise a recitation of structural features common to the members of a genus, which features constitute a substantial portion of the genus. See *Univ. of Cal. v. Eli Lilly*, 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997). This is analogous to enablement of a genus under section 112, ¶ 1, by showing the enablement of a representative number of species within the genus.

A chemical genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. If the genus has substantial variance, the disclosure must describe a sufficient number of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not specifically define what constitutes a representative number of species, the courts have indicated what does not constitute same. See, e.g., *In re Gostelli*, 10 USPQ 2d 1614, 1618 (Fed. Cir. 1989), holding that the disclosure of two chemical compounds within a subgenus did not adequately describe such subgenus.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include the level of skill and knowledge in the art, partial structure, physical and /or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the

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art to the conclusion that the applicant was in possession of the claimed species is sufficient. MPEP 2163.

Here the specification does not provide a reasonably representative disclosure of useful "monoterpenes." Generally, monoterpenes embody a huge genus inclusive of many different compounds having widely divergent structures and functions. (Applicant will note that claim 21 is not rejected here.) No reasonable correlation between structure and function has been established and disclosed as required by the case law and MPEP cited above.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 recites the limitation "said monoterpene moiety" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 39 recites the limitation "said inflammatory responses" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Nonstatutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

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obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 9, 10, 21-32, 39-43, 46 and 48-51 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9, 16-21 of U.S. Patent No. 6,962,720. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '720 patent and the instant claims both claim a method of treating inflammation in a subject by administering a monoterpene. The '720 does not teach that the monoterpene moiety is a cis or trans isomer, but compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. (See MPEP 2144.09.) Therefore, isomers of the moiety of the '720 patent are obvious. The concentration of the monoterpene composition is also obvious over the '720 patent since this is simply an attempt to

optimize results, which is well within the purview of the artisan. See *In re Aller*, 220 F.2d 454, 456 (105 USPQ 233).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1, 2, 9, 10, 21, 24-28, 31-32, and 40-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Arntzen et al., (US 6,444,233).

Arntzen et al., teach novel saponin mixtures and compounds that contain a triterpene moiety where monoterpenes are attached via a sugar or other linking group. (See Abstract; see also col. 3, lines 1-17.) They teach that the compounds are potent inhibitors of transcription factor NF-kB, which plays an important role in the inflammatory response. (See col. 69, lines 54-65.) They teach that the compounds treat atherosclerosis. (See col. 70, line 44.) They teach the compounds may be administered parenterally through injection, including directly into a disease site, orally, or topically. (See col. 50, lines 58-62; see col. 52, lines 8-11 and 21-26.) They also teach that the compounds are administered in pharmaceutical form suitable for injection in sterile aqueous solutions containing an oil, as per claims 51 and 52. (See col. 51, lines 12-16.) They show in Figs. 46A-D how the compounds inhibit induction of iNOS. (See col. 15, lines 40-42.) The composition would inherently inhibit COX-2 since, iNOS and COX-2

are both mediators of inflammation, sharing the similarities in mechanism of expression, as is well known¹.

The reference anticipates the instant claims insofar as it teaches a monoterpene composition, which is useful for treating inflammation, and that inhibits NF-kB.

Claim 1, 2, 9, 10, 21, 24-28, 31-32, and 40-52 are rejected under 35 U.S.C. 102(a) as being anticipated by Arntzen et al., (WO 1999/59578).

Arntzen et al., teach novel saponin mixtures and compounds that contain a triterpene moiety where monoterpenes are attached via a sugar or other linking group. (See Abstract; see also pg. 4, lines 14-26.) They teach that the compounds are potent inhibitors of transcription factor NF-kB, which plays an important role in the inflammatory response. (See pg. 111, lines 10-18.) They teach that the compounds treat atherosclerosis. (See pg. 112, line 24.) They teach the compounds may be administered parenterally through injection, including directly into a disease site, orally, or topically. (See pg. 83, lines 4-7; see pg. 85, lines 7-11 and 18-20.) They also teach that the compounds are administered in pharmaceutical form suitable for injection in sterile aqueous solutions containing an oil, as per claims 51 and 52. (See pg. 83, lines 21-24.) They show in Figs. 46A-D how the compounds inhibit induction of iNOS. (See pg. 23, lines 1-5.) The composition would inherently inhibit COX-2 since, iNOS and

¹ See Kun (US 5,908,861), at col. 19, lines 52-65.

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COX-2 are both mediators of inflammation, sharing the similarities in mechanism of expression, as is well known².

The reference anticipates the instant claims insofar as it teaches a monoterpene composition, which is useful for treating inflammation, and that inhibits NF-kB.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

² Ibid.

Claims 22-23, 29-30 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arntzen et al., (WO 1999/59578) as applied to claims 1, 2, 9, 10, 21, 24-28, 31-32, and 40-52 above.

Arntzen et al., in addition to that taught above, teaches a concentration of 1.56ug/ml, which is enough to effectively treat a number of cancer cell lines. (Se pg. 136, line 7.)

Arntzen et al. differs from the instant claims insofar as it does not teach cis-, trans-, optical-, or stereo- isomers of the of monoterpene as part of the composition. They also do not teach a concentration for effectively treating inflammation.

However, compounds, which are position isomers (compounds having the same radicals in physically different positions on the same nucleus), are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. (See MPEP 2144.09.) Therefore, isomers of the composition of Arntzen et al. are *prima facie* obvious. Moreover, administering the the monoterpene composition to a cell at a concentration from 0.5-2.0ug/ml is also obvious. A person having ordinary skill in the art would have reasonably expected success in administering 1.56ug/ml of the composition to a cell to treat inflammation since, Arntzen et al. teach that inflammation plays a central role in carcinogenesis. (See pg. 111, lines 15-18.) The connection between inflammation and carcinogenesis provides the basis for similarly administering of a composition that is known to treat both cancer and inflammation.

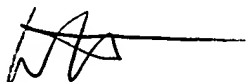
Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 270-3287. The examiner can normally be reached on 8:00am-4:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Walter E. Webb
Patent Examiner
AU 1612



Frederick F. Krass
Supervisory Patent Examiner
AU 1612

